



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 July 2025
EMA/HMPC/10134/2024
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Fragaria vesca* L.;
Fragaria moschata Weston; *Fragaria viridis* Weston;
Fragaria x ananassa (Weston) Duchesne ex Rozier, folium
Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	July 2015 September 2015 November 2015 May/June 2016 September 2016 November 2016 January 2017 March 2017 May 2017 September 2017 November 2017 January 2018
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	27 March 2018
Start of public consultation	15 April 2018
End of consultation (deadline for comments)	15 July 2018
Re-discussion in MLWP	September 2018
Adoption by HMPC Monograph (EMA/HMPC/432278/2015) Assessment Report (EMA/HMPC/432276/2015) List of References (EMA/HMPC/432277/2015) Overview of Comments received during the public consultation (EMA/638127/2018) HMPC Opinion (EMA/HMPC/811721/2018)	20 November 2018
First revision	
Discussion in HMPC	January 2024 March 2024 May 2024



	July 2024 September 2024 November 2024 January 2025 March 2025 May 2025 July 2025
Adopted by HMPC for release for consultation	9 July 2025
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Keywords	Committee on Herbal medicinal products; HMPC; European Union herbal monographs; herbal medicinal products; traditional herbal medicinal products; traditional use; <i>Fragaria vesca</i> L.; <i>Fragaria moschata</i> Weston; <i>Fragaria viridis</i> Weston; <i>Fragaria x ananassa</i> (Weston) Duchesne ex Rozier folium; wild strawberry leaf
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BG (bългарски): Горска ягода, лист	LT (lietuvių kalba): Žemuogių lapai
CS (čeština): jahodníkový list	LV (latviešu valoda): Meža zemenes lapas
DA (dansk): Jordbærblad	MT (Malti): werqa tal-Frawli
DE (Deutsch): Erdbeerblätter	NL (Nederlands): Bosaardbei
EL (elliniká): χαμαϊκεράσου εδωδιμου φύλλο	PL (polski): Liść poziomki
EN (English): wild strawberry leaf	PT (português): morangueiro-bravo, folha
ES (español): fresa, hoja de	RO (română): frunză de frag
ET (eesti keel): maasikaleht	SK (slovenčina): list jahody
FI (suomi): ahomansikka, lehti	SL (slovenščina): list navadnega jagodnjaka
FR (français): fraisier (feuille de)	SV (svenska): smultron, blad
HR (hrvatski): list šumske jagode	IS (íslenska):
HU (magyar): erdei szamóca levél	NO (norsk): markjordbærblad
IT (italiano): Fragola foglia	

European Union herbal monograph on *Fragaria vesca* L.; *Fragaria moschata* Weston; *Fragaria viridis* Weston; *Fragaria x ananassa* (Weston) Duchesne ex Rozier, folium

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1,2}

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC <i>Fragaria vesca</i> L.; <i>Fragaria moschata</i> Weston; <i>Fragaria viridis</i> Weston; <i>Fragaria x ananassa</i> (Weston) Duchesne ex Rozier, folium (wild strawberry leaf) (i) Herbal substance Not applicable ii) Herbal preparations Comminuted herbal substance.

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1)

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
² The material complies with the Austrian Pharmacopoeia monograph (ÖAB 2013:076)

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>

4.2. ***Posology and method of administration***³

Well-established use	Traditional use
	<p>Posology</p> <p>Indication 1)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Herbal tea: 5 – 10 g of comminuted herbal substance in 200 ml of water as a decoction. Drink the prepared decoction 2 - 3 times daily.</p> <p>Indication 2)</p> <p><i>Adolescents and adults</i></p> <p>Herbal tea: 4 - 5 g of comminuted herbal substance in 150-200 ml of boiling water as an herbal tea infusion or decoction. In adolescents drink the half of the prepared tea, 2 - 3 times daily. In adults drink the whole prepared tea as a single dose, 2 - 3 times daily.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>Indication 1)</p> <p>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

³ For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	<p>Indication 2)</p> <p>If the symptoms persist longer than 3 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indication 1)</p> <p>To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.</p> <p>If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Because adequate fluid intake is required during treatment, <i>Fragaria vesca</i> L.; <i>Fragaria moschata</i> Weston; <i>Fragaria viridis</i> Weston; <i>Fragaria x ananassa</i> (Weston) Duchesne ex Rozier, folium (wild strawberry leaf) is not recommended for patients with conditions where reduced fluid intake is advised.</p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 2)</p> <p>If diarrhoea recurs or bloody stools occur, a doctor or a qualified health care practitioner should be consulted.</p> <p>The use in children under 12 years of age has not been established due to the lack of adequate data.</p>

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	No interaction studies have been performed.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No information available.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

09 July 2025